



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

**MAY 24 2004**

Barco NV Barcoviev  
% Mr. Frank Ferguson  
Official Correspondent  
Ferguson Medical  
12200 Academy Road NE #931  
ALBUQUERQUE NM 87111

Re: K040365

Trade/Device Name: Color Coronis 2MP Medical Flat Panel Display System  
Regulation Number: 21 CFR 892.2050  
Regulation Name: Picture archiving and communication system  
Regulatory Class: II  
Product Code: 90 LLZ  
Dated: February 1, 2004  
Received: February 13, 2004

Dear Mr. Ferguson:

This letter corrects our substantially equivalent letter of April 28, 2004, regarding a typographical error. The word "Color" was omitted from the trade name and has since been corrected.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

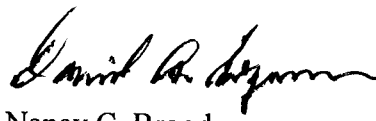
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4654. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

  
for Nancy C. Brogdon

Director, Division of Reproductive,  
Abdominal, and Radiological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

510(k) Number (If known): K040365

Device Name: Coronis 2MP Medical Flat Panel Display System

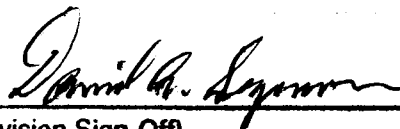
Indications For Use:

The Coronis 2MP Medical Flat Panel Display System is intended to be used in displaying and viewing digital images (excluding digital mammography) for review and analysis by trained medical practitioners.

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

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Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)

Division of Reproductive, Abdominal,  
and Radiological Devices

510(k) Number K040365

Prescription Use XX  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use \_\_\_\_\_

APR 28 2004

**510(K) SUMMARY**

K040365

|                                |                                                                                                                                                |
|--------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------|
| Manufacturer:                  | Barco NV Barcoviev<br>Theodoor Sevenslaan 106<br>8500 Kortrijk<br>Belgium                                                                      |
| Submitted By:                  | Ferguson Medical<br>Consultant to Barco NV                                                                                                     |
| Contact Information:           | Phone: +32(0) 56 23 32 11<br>FAX: +32(0) 56 23 3 74                                                                                            |
| Classification Name:           | System, image processing                                                                                                                       |
| Common/Usual Name:             | Medical flat panel grayscale display, monitor,<br>display and others                                                                           |
| Proprietary Name:              | Color Coronis 2MP                                                                                                                              |
| Classification Number:         | 21 CFR 892.2050/Procode 90LLZ                                                                                                                  |
| Substantial Equivalence:       | Coronis 3MP Medical Flat Panel Display System<br>(K013922)                                                                                     |
| Device Description:            | Color Coronis 2MP is a digital image display<br>system                                                                                         |
| Intended Use:                  | The Color Coronis 2MP device is intended to be<br>used in displaying and viewing digital images<br>for review by trained medical practitioners |
| Technological Characteristics: | The Barcoviev Color Coronis 2MP device<br>consists of components to provide high<br>resolution visualization of digital images                 |